K092112

5. 510(k) Summary As Required By 21 CFR 807.92

OCT - 6 2009

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Date Prepared: July 09, 2009

Device Trade Name: BTI Dental Implant Tiny® Ø3.0

Common Name: IMPLANT, ENDOSSEOUS, ROOT-FORM

Substantial Equivalence: K022258 BTI Dental Implant System
K053355 BTI Interna Dental Implant System
K080396 OsseoSpeedTM Narrow

Device Description: The BTI Dental Implant Tiny® Ø3.0 is a self tapping, threaded, root-form dental implant intended for restoring missing teeth in partially or fully edentulous patients to restore the chewing capacity of patients. It is made of titanium and offers a variety of sizes including diameter: 3.0mm and lengths: 11.5, 13, 15mm

Intended Use: BTI Dental Implants Tiny® Ø3.0 are intended to be used to restore missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.
These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors.
Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

Technological Aspects: A comparison of the device features, intended use and other information demonstrate that the BTI Dental Implant Tiny® Ø3.0 substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Alfredo Gómez
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SPAIN

OCT - 6 2009

Re: K092112
Trade/Device Name: BTI Dental Implant Tiny® 3.0
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 22, 2009
Received: September 24, 2009

Dear Mr. Gómez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/Reporta Problem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_K092112

Device Name:_BTI Dental implant Tiny® 3.0

Indications For Use:

BTI Dental Implant Tiny® 3.0 are intended to be used to restore missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.

These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors.

Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

Prescription Use ___X____ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for NSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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